DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: root formation. Applicant's claim recites that subsequent root formation is optional to produce transformed plantlets of Guayule. "Plantlet" is a term of art, essentially meaning a miniaturized plant that is complete with all of its parts. By definition, a plantlet must necessarily have roots. Thus, the step of forming roots cannot be optional in the creation of a plantlet.

Applicant's arguments to the previous Office Action recite that this element of the claim is independent of the method of transformation claimed and thus there should be no requirement to include a missing step. The Examiner has considered this argument but finds in unpersuasive. The main thrust of Applicant's argument is that the placement of the semi-colon in the claim provides clarity for one of skill in the art -- that it indicates that there is an independent and optional step. The examiner disagrees. The claim, as written is confusing. The Examiner suggests that Applicant illustrate the optional nature of root formation by providing it as a step C or by omitting it from the claim and instead setting forth this aspect of the invention in a subsequent dependent claim. The Examiner finds the claim as written at present confusing because the

characterization of the method as a transformation method is set forth in the preamble, and as such, the phrase "thus producing transformed plantlets of Guayule." at the end of the claim as it is presently written seems to indicate that the purpose of the claimed method is to produce transformed Guayule plants, as opposed to simply transformed Guayule tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood in view of Backhaus et al. (United States Patent Number 5,633,433) Dastoor et al. (United States Patent Number 4,363,188), Sikora (United States Patent Number 4,983,729), Castillon et al. and Jorgensen (United States Patent Number 5,180,873.

Wood teaches transforming guayule leaf strips by saturating them in a solution of transformed *Agrobacterium* and then forming shoots and rooted plantlets from the transformed guayule tissue. For example, the article recites that the researchers "… developed a faster, easier way to move new genes into guayule tissue in the lab. Their procedure, ***patterned after one used by scientists elsewhere with other plant species*** [emphasis added by the examiner], relies on bathing pieces of leaves in a solution containing a reworked form of a microbe, *Agrobacterium tumefaciens*. The

modified bacterium has the experimental genes inside and can slip them into guayule cells. The leaf pieces are nurtured to form shoots and, later, roots. The team is apparently the first to use this approach successfully with guayule."

Woods does not teach controlled light conditions, specific light concentrations or the use of selectable media.

Backhaus et al. teach

Isolation of a guayule rubber particle protein gene (RPP) and use of the gene to transform plants. Column 3, lines 28-36 note that the RPP gene can be isolated and transferred and will express RPP enzyme in tobacco or "other plants such as guayule or *Hevea*, that already synthesize rubber with the intent of overexpressing RPP. The overexpressed RPP can then enhance rubber production in these plants."

In Column 16, lines 5-15 the recombinant plasmid is transferred to *Agrobacterium*, and is used to inoculate "one of numerous plant species, such as tobacco, sunflower or guayule… the resulting transformed plant then produces large quantities of RPP which, in turn, leads to rubber biosynthesis in its cells. Also in Column 16, lines 35-37 note specifically that tobacco plants are transformed by the leaf disk method.

Backhaus et al. do not teach controlled light conditions, specific light concentrations or the use of selectable media.

Dastoor et al. teach, as early as 1982, numerous motivations for transforming guayule. For example, in Column 1 lines 20-40: Dastoor et al. note that guayule is a native SW U.S. shrub that produces polymeric isoprene essentially identical to that

made by *Hevea* rubber tress in Southeast Asia. As recently as 1910 it was the source of half of the natural rubber used in the U.S. … demand for natural rubber is expected to produce shortages and rubber prices are expected to double by 1985 … natural rubber is required for many kinds of tires… it is technically possible to satisfy projected demand with synthetics, but the rise in world petroleum prices has prompted the rubber industry to look for alternative sources of nature rubber. The principal, if not the only such, source is Guayule….

In lines 50-55, Dastoor et al. go on to note: "Because natural Guayule has a two year harvest cycle and can only be grown in a few selected areas of warm climate regions in Arizona, California and Mexico there have been numbers attempts to speed up the growth rate and yield of valuable polyisoprene rubber contained in the plant... (lines 63-65) it is therefore desirable to provide a method for propagating Guayule in vitro in an industrial setting not limited to specific climate conditions and geographical location.

They set forth in Column 2, lines 10-17 "A further advantage of promoting in vitro propagation of Guayule callus and shoots is the potential cloning of a single species of Guayule known to have high rubber levels to produce many clones having the identical desired high rubber levels. These clones may then be planted, grown and harvested commercially."

Columns 3 and 4 teach that in guayule propagation and culture, various media and IAA and kinetin concentrations work. The explants used were shoots.

Finally, in Column 5, Dastoor et al. teach controlled light conditions of16 hours light, 8 hours of darkness.

Dastoor et al. teach that desire to modify and breed guayule for increased production of rubber has existed for 3 years, as has the technology to tissue culture guayule under controlled light conditions and with various media.

Sikora teaches a transformed host containing the rubber gene (column 1). Sikora teaches that *Hevea* and guayule are two plants that produce sufficient rubber for commercial purposes, noting :"Efforts have been made to increase production of rubber in rubber-producing plants … despite such efforts, however the amount of rubber such plants can produce or can be stimulated to produce is limited by the rate of rubber synthesis by the plant.

In Column 4, Sikora teaches that the transformed host may be a plant or *Agrobacterium*. In Column 8, Sikora teaches isolation of the DNA from guayule.

Sikora does not teach controlled light conditions.

Castillon et al. teach *In vitro* propagation of guayule using shoot cultures. Their purpose is to make modifications to known methods that improve shoot proliferation and simplify protocols for both rooting and acclimation of plantlets to greenhouse conditions.

On page 215, Castillon et al teach controlled light conditions of cool fluorescent light with 16 h photoperiod, and on page 216 they teach the same light conditions for shoot culture maintenance.

Greehouse transfer by Castillon et al. used ambient daylength but supported more lighting in overcast conditions.

Jorgensen teaches *Agrobacterium* transformation of leaf explants is known in the art as is tissue culture from leaf explants.

One of ordinary skill in the art would be motivated to transform guayule to produce more of the desired products of the plant. Numerous motivations are set forth in the references cited above. The method set forth in the claims would be obvious to one of ordinary skill in the art at the time the invention was made because it is a variant of known tissue culture and transformation methods. In fact, the Woods report cited that discloses much of the claimed method, recites that co-inventor Cornish's "procedure [was], patterned after one used by scientists elsewhere with other plant species." The Examiner notes that this publication pre-dates the filing of the instant application for patent by nearly 5 years.

As such, the claimed method/invention was *prima facie* obvious at the time it was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WENDY C. HAAS whose telephone number is (571)272-0976. The examiner can normally be reached from 10:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Grunberg can be reached on (571)272-0975 alternatively, the examiner's other supervisor, Joe Zhou can be reached at (571) 272-0724. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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